UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

GILEAD SCIENCES, INC., *et al.*, **Plaintiffs,** **v.** **SAFE CHAIN SOLUTIONS, LLC, *et al.*,** **Defendants.**	**Civil Action No. 21-cv-4106 (AMD)(RER)** **ECF CASE**

MEMORANDUM OF LAW IN SUPPORT OF SCRIPTS WHOLESALE INC.'S RENEWED MOTION TO VACATE OR AMEND THE ASSET FREEZE ORDER

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes and Rules and Other Authorities

INTRODUCTION

Defendant Scripts Wholesale, Inc. ("Scripts") renews its motion to vacate or otherwise modify the *ex parte* Asset Freeze Order entered against it on October 16, 2021. (Schurin Decl., ¶2, Ex. A).

A pre-judgment asset freeze is a "dramatic and extreme" remedy that cannot be continued in a case such as this, where the legal claims underpinning the asset freeze are not firmly established, and there is no evidence that Scripts will dissipate its assets. *See e.g.*, *Groupo Mexicano v. Alliance Bond Fund*, 527 U.S. 308, 144 L. Ed. 2d 319, 119 S. Ct. 1961 (1999). Indeed, "[a] Court may not enter a preliminary injunction simply to safeguard [a defendant's] assets in the event that [defendant is] ultimately held liable on these claims." *Spin Master v. Aciper*, 2020 US Dist. LEXIS 206278, at *8 (S.D.N.Y. 2020), *citing Dong v. Miller*, 2018 U.S. Dist. LEXIS 48506, at *9 (E.D.N.Y. 2018).

An asset freeze should only be maintained when the liability against a defendant is certain. Here, the Asset Freeze Order must be vacated because Gilead's claims for counterfeiting against Scripts will likely fail, as a matter of law, for at least three distinct reasons.

First, Gilead's counterfeiting claims, which are premised upon false pedigree documents, may be adjudicated solely by the Food and Drug Administration (hereinafter "FDA") under the Drug Supply Chain Security Act (hereinafter "DSCSA"), 21 U.S.C. §§ 360eee to 360eee-4. As discussed herein, there is no private right of action in DSCSA under which Gilead may assert the type of claim based on false pedigrees that Gilead now asserts against Scripts in this case.

Second, Gilead's claims for counterfeiting against Scripts based on Scripts' alleged use of false pedigrees will likely fail since Gilead's claims are premised upon a novel and flawed theory of counterfeiting under the Lanham Act. Gilead's counterfeiting claim is flawed because

the allegedly false pedigrees relate almost exclusively to genuine pharmaceutical products that are indisputably manufactured by Gilead. Thus, Gilead's claim primarily involves Scripts' purchase, advertising and sale of genuine Gilead pharmaceuticals in genuine Gilead packaging, which cannot constitute "counterfeiting" or sustain the Asset Freeze Order that Gilead acquired against Scripts on an *ex parte* basis.

Third, the use of a mark on a pedigree does not constitute "use" under §1127 (or §1116) of the Lanham Act and therefore for this additional reason cannot serve as the basis for Gilead's counterfeiting or infringement claims. Indeed, a pedigree is a document that accompanies the sale of Gilead medication as part of a business transaction. However, since the references to Gilead marks on a pedigree are not marks that are placed on "goods," "containers," "displays," or "tags or labels affixed thereto" they do not constitute a trademark use but are instead just descriptive uses. Such references cannot constitute "use" of a "counterfeit mark" as defined in §1116(d)(b)(i).

Since Gilead's counterfeiting claims against Scripts are based on these flawed theories of liability, Gilead can hardly contend that liability against Scripts for counterfeiting has been firmly established or is certain, which is required for the maintenance of an asset freeze order.

Scripts also notes that since the original filing of this motion Gilead has sought to transition its argument to one based on purportedly counterfeit or infringing "outserts" attached to the bottles. However, Gilead's effort to pivot away from the weak legal arguments upon which the asset freeze was granted in the first place is not compelling since Gilead has absolutely no direct evidence that any of the medications actually sold by Scripts had an incorrect outsert.

ARGUMENT

For the following reasons, the *ex parte* Asset Freeze Order entered against Scripts should now be vacated or at least substantially reduced.

I. THE BURDEN OF PROOF IS ON GILEAD TO MAINTAIN THE *EX PARTE* ASSET FREEZE AGAINST SCRIPTS

The Asset Freeze Order against Scripts was entered on an *ex parte* basis, and Scripts has not stipulated to the entry of any preliminary relief. Therefore, the burden remains on Gilead to prove the continued necessity of the Asset Freeze Order. *See*, *Spin Master v. Aciper*, 2020 U.S. Dist. LEXIS 206278, *9 (S.D.N.Y. 2020); and *BMaddox Enters., LLC v. Oskouie*, 2017 U.S. Dist. LEXIS 146766, *6 (S.D.N.Y. 2017) (citing cases). This makes sense since Scripts has not yet had the opportunity to contest Gilead's application for the asset freeze, and the Court has not previously made specific findings of fact justifying the asset freeze entered against Scripts.

None of the cases previously cited by Gilead remotely supports its position that the interim agreement reached by the parties to release some funds serves to shift the burden from Gilead to Scripts as to what remains in dispute. For example, in *Cartier Int'l B.V. v. Liu*, 2003 U.S. Dist. LEXIS 6381 (S.D.N.Y. 2003), a preliminary injunction was entered. After entering the injunction on the merits, the Court held that shifting the burden on a motion to vacate the asset freeze was appropriate since the defendant had every opportunity to contest the asset freeze but did not. Here, no such preliminary injunction has been entered against Scripts and, as a result, no such burden shifting has taken place.

II. GILEAD'S CLAIM OF COUNTERFEITING AGAINST SCRIPTS IS LIKELY SUBJECT TO DISMISSAL FOR FAILURE TO STATE A PLAUSIBLE CLAIM

The *ex-parte* Asset Freeze Order entered against Scripts should be vacated, or at least substantially reduced, since Gilead's claim of counterfeiting is subject to dismissal for failure to state a claim for three independent reasons.

A. Gilead's Claim for Counterfeiting Based on False Pedigrees Is Precluded Under DSCSA, 21 U.S.C. § 360eee to 360eee-4 a

Gilead's counterfeiting claim under the Lanham Act against Scripts is precluded as a matter of law because the facts that support Gilead's Lanham Act claims against Scripts fall within the domain of the FDA, which has exclusive authority to decide claims involving suspect pedigrees that are used to trace and verify the identity of drugs.

On November 17, 2013, Congress enacted the DSCSA. The DSCSA set forth new definitions and requirements for manufacturers, re-packagers, wholesale distributors, and dispensers to facilitate the tracing of products through the pharmaceutical distribution supply chain. In this regard, the DSCSA aims to regulate the drug supply chain by implementing a uniform, interoperable system to trace and verify the identity of a drug as it passes through a manufacturer, wholesale distributor, dispenser, or re-packager in the supply chain. *See e.g., In re Valsartan, Losartan & Irbesaratan Prods. Liab. Litig.*, 2020 U.S. Dist. LEXIS 238919, *56 (D.N.J. 2020). The purpose of Congress is the ultimate touchstone in every preemption case. *Id.*, at *49, *citing Wyeth v. Levine*, 555 U.S. 555 (2009). In this case, the DSCSA was enacted to protect consumers from products that may be counterfeit, stolen, contaminated, or otherwise harmful. In so doing, the DSCSA implemented a uniform national supply chain tracing policy, including the imposition of certain obligations (including pedigree requirements) in the distribution process, to fix the supply chain's vulnerability to counterfeit drugs. *Id.*, at 56-57.

Accordingly, the DSCSA clearly regulates pedigrees associated with pharmaceutical drugs. Therefore, a violation of the DSCSA's tracing requirements that is premised on creating or using false or incorrect pedigrees – which forms the core of Gilead's counterfeiting claim against Scripts – rightfully falls within the purview of the FDA and its oversight of the DSCSA, **not** the Lanham Act. In other words, Gilead's claim against Scripts for distributing pharmaceuticals with allegedly false or incorrect pedigrees is governed by the federal law designed to promote public health and safety, i.e., the DSCSA.

Although the DSCSA includes an explicit preemption clause confirming Congressional intent that the DSCSA preempts state law governing the distribution of pharmaceutical drugs [*see*, 21 U.S.C. §360eee-4(b)(1); *Matrix Distribs. v. N.A. of Bds. of Pharm.*, 2020 U.S. Dist. LEXIS 228271 (D.N.J. December 4, 2020)], Scripts is not aware of any reported decision holding that competing federal statutes, such as the Lanham Act, are also precluded by the DSCSA and the FDA's authority. Although, as discussed herein, it would be logical to find that to be the case.

Scripts is also not aware of any cases that sanction Lanham Act cases involving alleged DSCSA violations. Accordingly, it appears as if no specific precedent exists with regard to the interaction between the DSCSA and the Lanham Act. However, there are numerous cases dismissing Lanham Act claims on the grounds that they are precluded the Food, Drug and Cosmetic Act (hereinafter the "FDCA") which is somewhat analogous. *See e.g.*, *Amarin Pharma, Inc v. ITC*, 923 F.3d. 959, 967 (Fed. Cir. 2019) (allowing plaintiffs to shoehorn a question of regulatory compliance into the Lanham Act would require judges to make a "preemptive determination of how the FDA would interpret and enforce its own regulations").

In *Amarin*, the court held that plaintiff's Lanham Act claims were precluded by the FDCA and that the FDA was charged with the administration of FDCA. *Id.*, at 966. In *Amarin*, the defendant was accused of using false and misleading labels and advertisements. Plaintiff asserted that labeling the products as "dietary supplements" was literally false because the products could not meet the definition of "dietary supplement" as set forth in Section 201(ff) of the FDCA. *Id.*, at 967. Amarin's complaint relied on these alleged FDCA violations to support key elements of its false advertising claim under the Lanham Act. Accordingly, the Lanham Act claim was dismissed since it was precluded by the FDCA. Here, since Gilead's Lanham Act claim is undeniably premised on violations of the DSCSA, based on Scripts' alleged dealing with false or incorrect pedigrees, Gilead's claim will thus likely be precluded and ultimately dismissed as a matter of law just as Amarin's claim was dismissed since it was precluded by FDCA. Thus, insofar as Gilead's *ex parte* Asset Freeze Order is tied to its counterfeiting claim that is likely to be precluded, the Court should vacate the Asset Freeze Order.

In opposition to this argument, Gilead has previously relied on *Pom Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014). However, as *Amarin* makes clear, the Court after *POM Wonderful* did not open the door to Lanham Act claims based on proving (or prosecuting) FDCA violations and said nothing of the DSCSA. *Amarin*, 923 F3d at 969 (Fed. Cir. 2019). Instead, *Amarin* and cases like it suggest that since the DSCSA explicitly governs the distribution of products with allegedly false pedigrees that are used to track drugs, the same result of dismissal should apply here with respect to the alleged violation of the DSCSA (see *Methods Pharm., LLC v. H-2 Pharma, LLC*, 2022 U.S. Dist. LEXIS 19541 (M.D. Ala. Feb. 3, 2022); *Hi-Tech Pharm., Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323 (N.D. Ga. 2016); and *JHP Pharm., Ltd. Liab. Co. v. Hospira, Inc.*, 52 F. Supp. 3d 992 (C.D. Cal. 2014), precluding Lanham Act claims

where they rest on FDA definitions, interpretations and determinations regarding safety, legality and classification of drugs and drug label contents). Accordingly, Gilead should not be permitted to bring claims involving DSCSA violations that are cloaked in a claim of counterfeiting under the Lanham Act.

Gilead's reliance on *Pom Wonderful LLC* to refute this strong preclusion argument is without merit. Gilead's argument is erroneous because it presupposes, without support, that the holding of *Pom Wonderful* extends beyond food labelling and into the FDA's regulation of drugs where the FDA's powers are far more extensive. Evidence that such an extension would be considered unwarranted by the Supreme Court can even be found in its decision in *Pom Wonderful* wherein the Court specifically noted that the FDA has a less extensive role in food labels, specifically juice labels, as compared to its regulation of drug labels. See, *Pom Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014) (The FDA does not preapprove juice labels which "is consistent with the less extensive role the FDA plays in the regulation of food than in the regulation of drugs"). Thus, it can be persuasively argued that the public interest in giving the FDA exclusive reign to regulate drug pedigrees is far too important to give to manufacturers who have a business interest, rather than a public safety interest, and certainly more important than the regulation of juice labels.

The DSCSA was enacted with the intent for FDA and Department of Justice ("DOJ") oversight to be the exclusive means of enforcing product tracing requirements, including pedigrees. For example, while the FDA does not require pre-approval for pedigrees, it does require the provision of pedigrees. Further, the FDA plainly authorizes creation of a single pedigree document (See, Schurin Decl., ¶3, Ex. B), and determines what constitutes compliance with and violation of DSCSA requirements, including identifying whether a product is suspect or

illegitimate, whether a duty has been triggered and satisfied regarding verification (including quarantine and investigation), and whether to and what penalty to impose for a violation (See, Schurin Decl., ¶4, Ex. C). Indeed, "[t]he question of legality directly implicates the FDA's rulemaking authority." *Hi-Tech Pharm., Inc. v. Hodges Consulting, Inc.*, 230 F. Supp. 3d 1323, 1330 (N.D. Ga. 2016) *citing JHP Pharms., LLC*, 52 F. Supp. 3d 992 at 1004.

A counterfeit pedigree is a violation of the DSCSA. The purpose of a pedigree is not to protect the Lanham Act's commercial interests regarding consumer perception. Rather, the pedigree requirement is intended to serve the DSCSA's public safety interest to secure and verify the supply chain for prescription drug products. Gilead's claims relating to pedigrees would not exist but for the DSCSA and the FDA's implementation of the DSCSA's product tracing and pedigree requirements. Like a wholesale license, pedigrees are a regulatory requirement.

If allowed to proceed, Gilead's Lanham Act claims would possibly undermine prior judgments and determinations made by the FDA. For example, by providing wholesale distributors with a choice for compliance with the pedigree requirement (to either provide prior pedigrees received or create a new single pedigree document based on the information received), the FDA has already made a determination on the subject of this dispute (Ex. B). This creates a potential conflict. As in *Geier v. Am Honda. Motor Co.*, the federal policy at issue provides options for compliance, and the conflicting private cause of action attempts to take that option away. 529 U.S. 861, 120 S. Ct. 1913 (2000) Since Gilead's counterfeiting claims under the Lanham Act would take that option away, and so directly conflict with the FDA's policy choice to provide options for legal compliance with the DSCSA product tracing and pedigree requirements, Gilead's Lanham Act claims ought to be precluded. See also, *JHP Pharms., LLC*, 52 F. Supp. 3d 992 at 999, citing *POM Wonderful*, 134 S. Ct. at 2241 (a Lanham action might be

barred where the agency enacted a regulation deliberately allowing manufacturers to choose different options).

Finally, while the DOJ may have indicted and prosecuted conspiracy leaders who created false pedigrees for diverting products and impersonating legitimate suppliers to defraud their wholesale customers including Scripts, it is noteworthy that the DOJ has so far refused to bring a single charge for criminal counterfeiting against anyone on the basis of a counterfeit pedigree (See e.g., Schurin Decl., ¶¶6-8, Exs. E, F, and G). As in *PhotoMedex, Inc. v. Irwin*, enforcement power is reserved to the federal government. 601 F.3d 919 (9th Cir. 2010) at 930. Gilead is "not permitted to circumvent the FDA's exclusive enforcement authority by seeking to prove that Scripts violated the FDCA, when the FDA did not reach that conclusion." *Rebotex Repair , LLC v. Intuitive Surgical, Inc.*, 2022 U.S. Dist. LEXIS 142861, at *14 (M.D. Fla. Aug. 10, 2022), *citing PhotoMedex v. Irwin*, at 928. Since Gilead's claims would directly conflict with the DOJ's policy choice not to prosecute criminal counterfeiting claims for authentic but diverted products based on false pedigrees in any case, Gilead's Lanham Act claims ought to be precluded. To permit Gilead to proceed with a private Lanham Act claims based on the DSCSA pedigree requirements, where the FDA and DOJ refused to take further action after investigation, would, in effect, permit Gilead to assume enforcement power and make a decision that the FDA and DOJ itself did not make. We respectfully submit that this could obstruct the federal regulation of the DSCSA's product tracing requirements.

B. Gilead Cannot Assert a Plausible Claim for Counterfeiting Based Upon a Suspect Pedigree

Even if the Court decides that Gilead's counterfeiting claim based on false or incorrect pedigrees should not be precluded by the DSCSA, the Court must still vacate the Asset Freeze

Order since there is no cognizable claim for counterfeiting under the Lanham Act based on a false pedigree.

We must start with the understanding that an asset freeze order is an extreme provisional remedy. *Groupo Mexicano v. Alliance Bond Fund*, 527 U.S. 308, 144 L. Ed. 2d 319, 119 S. Ct. 1961 (1999). In order to qualify for such extraordinary relief under the Lanham Act, establishing a claim for mere trademark infringement is entirely insufficient. Rather, Gilead must have established an unquestionable claim for counterfeiting under the Lanham Act. *See*, 15 U.S.C. §1116(d). In the instant case against Scripts, Gilead's claim of counterfeiting under the Lanham Act was premised upon the notion that a pedigree with false information constitutes counterfeiting under the Lanham Act. This is a flawed theory of trademark law which stands entirely unsupported by any precedent.

For example, only in extreme cases does trademark infringement rise to the level of counterfeiting. Generally, counterfeiting is considered a first-degree form of infringement that aims to trick a consumer into believing that he or she is getting the genuine article, rather than a "colorable imitation." *Gucci Am., Inc. v. Guess?, Inc.*, 868 F. Supp. 2d 207, 242 (S.D.N.Y. 2012) (*citing* 4 *McCarthy on Trademarks and Unfair Competition* § 25:10). The Second Circuit has held that unless a defendant engages in exact copying of entire products, trademark counterfeiting claims should be addressed under "traditional infringement principles." *Gucci Am.*, at 253. As such, courts generally reserve this designation for products that are "stitch-for-stitch *copies* of those of another brand." *Id.*, at 242. Counterfeiting is a much more grievous violation than lower forms of infringement, as it may expose the infringer to treble or statutory damages and attorney fees, *see* 15 U.S.C. § 1117(b), and it may provide for extraordinary provisional relief like an asset freeze, *see* 15 U.S.C. § 1116(d)(1).

Section 45 of the Lanham Act provides the basic definition of what constitutes a "counterfeit." A "counterfeit" is defined as a "spurious mark which is identical with, or substantially indistinguishable from a registered mark." *See*, 15 U.S.C. §1127. "Spurious" is defined as: "Deceptively suggesting an erroneous origin; fake." Black's Law Dictionary (10th ed. 2014). In addition, a "counterfeit mark" is elsewhere defined in the Lanham Act as "a counterfeit of a mark that is registered on the principal register in the [USPTO] for such goods or services sold, offered for sale, or distributed and that is in use…" 15 U.S.C. § 1116(d)(1)(B)(i). Although this portion of the U.S. Code does not specifically use the word "spurious," the definition set forth in § 1127 is read into § 1116(d)(1)(B)(i). 130 Cong. Rec. H12076, at H12079 (daily ed. Oct. 10, 1984); 7 *McCarthy on Trademarks* Appendix A8 (5th ed.).

Notably, a counterfeit mark is **not**:

> [A] mark or designation used on or in connection with goods or services of which the manufacture or producer was, at the time of the manufacture or production in question authorized to use the mark or designation for the type of goods or services so manufactured or produced, by the holder of the right to use such mark or designation.

15 U.S.C. § 1116(d)(1)(B). If a mark is counterfeit, it is always infringing, but the inverse is not necessarily true.

The definition of the term "counterfeit mark" was also discussed in a Joint Statement on Trademark Counterfeiting Legislation. *See*, 130 Cong. Rec. H12076, at H12078 (daily ed. Oct. 10, 1984). As stated in that Joint Statement, the re-sale of goods originally manufactured by the trademark holder, i.e., genuine goods originating from the manufacturer, such as those present in situations of "parallel imports" and "gray market goods" are specifically excluded from consideration as "counterfeit." *See*, 30 Cong. Rec. H12076, at H12078 (daily ed. Oct. 10, 1984) ("The term 'counterfeit mark' in this bill also excludes the marks on so-called 'parallel imports' or 'gray market' goods – that is, trademarked goods legitimately manufactured and sold overseas

and then imported into the United States outside the trademark owner's desired distribution channels (*see generally, Bell & Howell: Mamiya Co. v. Masel Supply Co.*, 719 F.2d 42 (2d Cir. 1983)"). This legislative history clearly warns courts against expanding the definition of "counterfeit" – and the extreme provisional remedies that go along with it – far beyond the traditional understanding that the term "counterfeit" applies to goods that are themselves not genuine because they are not manufactured by the brand-holder.

In all, for counterfeiting liability to attach, the goods themselves need to be non-genuine, meaning that the goods generally need to have been manufactured or originated from an individual or entity other than the owner of the mark. This makes sense since "the purpose of trademark law is not to guarantee genuine trademarks but to guarantee that every item sold under a trademark is the genuine trademarked product, and not a substitute." *General Electric Company v. Speicher*, 877 F.2d 531, 534 (7th Cir. 1989).

It is exceptionally rare for a court to even entertain a claim of counterfeiting in circumstances where the product itself is genuine. Indeed, Scripts is aware of no reported case, in any jurisdiction, where a claim of counterfeiting under the Lanham Act was established based upon an alleged suspect pedigree, and to Scripts' knowledge, no such case exists. Nevertheless, Gilead now asks this Court to maintain the most extreme remedy available under the Lanham Act against Scripts, i.e., an *ex parte* Asset Freeze Order, based upon a flawed and newfangled theory of what may constitute a counterfeit under the Lanham Act.

Therefore, Scripts respectfully submits that Gilead's theory of liability for counterfeiting based on a suspect pedigree constitutes an extreme expansion of what a counterfeit is under the Lanham Act. Here, the alleged use of a false or incorrect pedigree clearly falls outside the scope

of the definition of "counterfeit," since any purported "use"[1] by Scripts of the Gilead marks and/or slogans is in connection with the advertising and sale of authentic Gilead drugs. In other words, since Gilead's counterfeiting claim against Scripts for false pedigrees are not premised upon anything other than their use in connection with genuine and authentic Gilead drugs, Gilead's counterfeiting claim will likely fail as a matter of law. As it was made clear in the Joint Statement on Trademark Counterfeiting Legislation, the re-sale of goods originally manufactured by the trademark holder are specifically excluded from consideration as "counterfeit." *See also, United States v. Hanafy*, 302 F.3d 485 (5th Cir. 2002) (affixing a trademark to shipping trays containing parallel goods does not constitute counterfeiting since the goods themselves are entirely genuine and authentic).

Gilead's contention that false pedigrees constitute counterfeits is also undermined by inconsistent statements from its counsel in correspondence to pharmacies that have purchased Gilead drugs from Scripts. For example, in a letter dated October 25, 2021, from Gilead's counsel to Hoover Drugs LLC, Gilead's counsel states, in relevant part:

> We have not yet confirmed whether the Gilead-branded medicines sent to you are counterfeit. However, **we have confirmed that other Gilead-branded medicines-including BIKTARVY® and DESCOVY®-sold by Scripts are counterfeit and could cause harm to patients. Moreover, we have confirmed that numerous Gilead-branded medicines sold by Scripts were accompanied by false pedigree documentation or "T3s."**

(Schurin Decl., ¶ 5, Ex. D) Based on this correspondence, Gilead's counsel does not itself consider false pedigree documentation or "T3s" to render an otherwise genuine bottle of Gilead medication to be counterfeit. If false pedigrees automatically render genuine medication counterfeit, there would be no need to also state that Scripts sold Gilead medication with false

[1] As discussed in the following section, Scripts does not concede that any references to Gilead marks or slogans on a pedigree/T3 constitute "use" as required under the Lanham Act.

pedigree documentation, and the last sentence in the quote above would be entirely unnecessary. Gilead's counsel would have simply stated in his letter that Gilead "has confirmed that other Gilead-branded medicines…sold by scripts are counterfeit and could cause harm to patients."

This is further confirmed by the very next paragraph which begins:

> Because there is a chance that the Gilead-branded medicines sold to you by Scripts **are counterfeit and/or are accompanied by falsified pedigree documents**, those medicines should be considered "suspect products" pursuant to the Drug Supply Chain Security Act (DSCSA).

Id. Again, if false pedigree documents render genuine medication counterfeit all on its own, then there would be no need for Gilead's counsel to stress that the Gilead medication sold by Scripts may be counterfeit **and** are accompanied by falsified pedigree documents. Clearly, Gilead itself understands that a counterfeit constitutes something different than a product accompanied by an incorrect or false pedigree. Therefore, based on its own correspondence sent to pharmacies long after this case commenced, Gilead cannot seriously contend that false pedigree documentation standing alone can support a claim of counterfeiting under the Lanham Act.

The novelty of Gilead's argument is also evidenced by the lone case it cited in support of its application for *ex parte* relief, *Coty, Inc v. Cosmopolitan Cosmetics, Inc.*, 432 F. Supp. 3d 345, 349, 352-353 (S.D.N.Y. 2020). In *Coty*, the allegations were that the defendant "mutilated" packages of perfume bottles by removing the codes placed there by the manufacturer. In denying defendants' motion to dismiss, the court held that such a claim could *plausibly* be considered counterfeiting so it would not grant the defendants' motion to dismiss for failure to state a claim. Notably however, no decision on the merits was ever rendered since the case was ultimately settled on a confidential basis. Moreover, no provisional relief was granted in favor of plaintiffs in *Coty*. Thus, not only did *Coty* not involve a request for extreme relief, it also did not involve

pharmaceuticals, false pedigrees or a product that may directly impact public health and safety. Had Gilead been in possession of any better authority, it surely would have cited it in support of its application for the Asset Freeze Order. That none exists demonstrates that the merits of Gilead's counterfeiting claim against Scripts are far from solid. Insofar as Gilead's *ex parte* Asset Freeze Order is tied to its counterfeiting claim against Scripts that may very well fail since the accused products marketed and sold by Scripts are genuine and authentic Gilead drugs, the Court should vacate the Asset Freeze Order.

Finally, in response to this motion, Gilead will likely raise two independent instances of Script's unintentional sale of adulterated drugs, each of which occurred well before Gilead's application for the *ex parte* Asset Freeze Order. These events were addressed properly with the FDA and with Gilead, as well. Moreover, if Gilead thought that these two instances warranted urgent action in the form of a seizure or asset freeze, **Gilead would not have waited more than a year to seek the *ex parte* relief that it obtained herein**. Indeed, to the extent that Gilead wishes to rely on Scripts' prior acts that took place long before the acts complained of in this litigation, Gilead's unexcused delay would constitute a valid defense of laches in the Second Circuit, barring the preliminary relief sought by Gilead. *See*, *Citibank N.A. v. Citytrust*, 756 F.2d 273 (2d Cir. 1985). In addition, if these two instances formed the basis for Gilead's claim of counterfeiting, it could not possibly support freezing over $5 million, since the profit that Scripts earned from the sale of these two bottles are *de minimis* compared to the amount of money that has been frozen.

C. Pedigrees Do Not Constitute "Use in Commerce" Pursuant to 15 U.S.C. § 1127

Lastly, in this instance Gilead cannot satisfy the 'use in commerce' requirement of 15 U.S.C. § 1114(1)(a) to establish a counterfeiting claim. To constitute a "trademark use" necessary

to support a counterfeiting claim, the mark must be "placed in any manner **on the goods or their containers or the displays associated therewith or on the tags or labels affixed thereto**…." *See* 15 U.S.C. § 1127. (Emphasis added) In other words, in the context of Gilead's claims against Scripts, Gilead's marks are not in "use" if they are not placed on the "goods," "containers," "displays," or "tags or labels affixed thereto." Here, the reference to Gilead marks on pedigrees simply do not meet the statutory definition for "use" under the Lanham Act.

The nature of use that constitutes "use in commerce" under the Lanham Act is well-established. In a recent decision, one court has held that "documents associated with product shipments and sales, such as receipts, invoices, bills of lading, and web pages," would only constitute use in commerce if "the goods themselves are of such a nature that a mark cannot physically be affixed to them." *Est Inc. v. Royal-Grow Prods.*, 526 F. Supp. 3d 943, 954 (D. Kan. 2021). However, use of the mark **on documents merely associated with a product** cannot be used to satisfy the "use in commerce" requirement of § 1127. *Id.* (*citing In re Chi. Rawhide Mfg. Co.*, 59 C.C.P.A. 963, 455 F.2d 563, 564-65 (C.C.P.A. 1972) (use of mark on invoice which accompanies goods is not "use in commerce" under the Lanham Act); *In re Bright of Am., Inc.*, 1979 TTAB LEXIS 100, *5 (Trademark Trial & App. Bd. 1979) (finding that materials used to conduct business such as invoices, billboards, way bills and business stationery are insufficient to establish "use")). Other cases involving receipts, brochures and packing inserts have reached similar conclusions, finding that these kinds of uses do not constitute "use in commerce." *See e.g., Kische USA, LLC v. Simsek*, 2017 U.S. Dist. LEXIS 196191, *25 (W.D. Wash. 2017); *VersaTop Support Sys., LLC v. Ga. Expo Inc.*, 2017 U.S. Dist. LEXIS 57427, *4-5 (D. Or. 2017).

Here, even though pedigrees may accompany sales, the use of a mark on a pedigree does not constitute "use" under § 1127 (or § 1116) and therefore cannot serve as the basis for Gilead's

counterfeiting claim. Simply put, a pedigree does not include the use of counterfeit marks. Indeed, since the references to Gilead marks on a pedigree are not marks that are placed on "goods," "containers," "displays," or "tags or labels affixed thereto," such references cannot constitute use of a "counterfeit mark" as defined in §1116(d)(b)(i), which also requires "use."

Scripts' contention that dealing in goods with false pedigrees does not constitute counterfeiting under the Lanham Act is also corroborated by the *Mainspring* case that Gilead has previously referenced. In particular, the indictment in the *Mainspring* case discusses the DSCSA and its requirements that distributors provide transaction documentation, i.e., pedigree. (Schurin Decl., ¶5, Ex. D). The indictment further describes the specific acts committed by the Mainspring Defendants in creating false paperwork and transaction documents to defraud their customers. (Schurin Decl., Ex. D). However, there is not a single charge of criminal counterfeiting under 18 U.S.C. § 2320. (Ex. D). Had a charge of counterfeiting actually been appropriate, it would have been elementary for the government to assert it in any of the related indictments (Schurin Decl., ¶¶6-8, Exs. E, F, G).

Cases previously cited by Gilead in original briefing on this motion – e.g., *State of Idaho Potato Comm'n, Monsanto, Johnson & Johnson* (*Gilead Opp. Br.*, pp. 17-20) – are also inapposite and their insignificance for purposes of this motion is not in serious dispute. In each of those cases, there was a counterfeit use of a mark in commerce since the counterfeit marks were applied to packaging, which are "containers" under § 1127.

Finally, Gilead's theory of counterfeiting via pedigree must also be rejected because the names of the manufacturer and that of the drugs (e.g., BIKTARVY®, GENVOYA®) which appear on the pedigrees are entirely truthful, accurately describing the contents of the bottles of

medication that are sold by Scripts. Although Gilead contends that the transaction history on pedigrees is inaccurate, the trademark source-identifying information is actually not under attack.

III. GILEAD HAS NOT DEMONSTRATED THAT SCRIPTS WILL DISSIPATE OR SECRETE ITS ASSETS

To justify the continuation of the Asset Freeze Order, Gilead also bears a separate and significant burden of proving that Scripts intends to dissipate assets in the absence of a freeze in order to frustrate any potential judgment against it. *Spin Master v. Aciper*, 2020 U.S. Dist. LEXIS 206278 (S.D.N.Y. Nov. 4, 2020) (denying request to continue asset freeze and enter preliminary injunction since plaintiffs point to no conduct that would suggest intent to frustrate a potential future judgment for counterfeiting). Indeed, it is Gilead's high burden to demonstrate that "a significant risk that the irreparable harm exists where, but for the grant of equitable relief, there is a substantial chance that upon final resolution of the action the parties cannot be returned to the positions they previously occupied." *Sterling Ornaments Pvt. Ltd. V. Hazel Jewelry Corp.*, 2015 U.S. Dist. LEXIS 77331, at *2 (S.D.N.Y. 2015) (denying request for temporary restraining order freezing defendants' assets). Thus, even assuming that Gilead has made a *prima facie* case of counterfeiting against Scripts, which is very much disputed, even a prima facie case of counterfeiting does not give rise to a presumption that a defendant's cash assets need to continue to be restrained to prevent irreparable harm. And while a prima facie case of counterfeiting or infringement may in some cases give rise to a presumption of irreparable harm, it does not give rise to a presumption that a defendant's cash assets need to continue to be restrained to prevent irreparable harm. *See e.g., Kebapci v. Tune Core Inc.*, 2016 U.S. Dist. LEXIS 159054, at *4 (E.D.N.Y. 2016) (denying preliminary injunction to freeze assets where no evidence beyond conclusory allegations that would dissipate or transfer assets to avoid any future judgment). In

Sterling Ornaments, even the wrongful use of corporate funds was not deemed evidence of an intent to frustrate a future judgment. 2015 U.S. Dist. LEXIS 77331, at *3-4 (S.D.N.Y. 2015).

Here, there is no evidence in the record that Scripts would dissipate its assets in order to frustrate any future judgment. In its recently filed Fifth Amended Complaint [Docket No. 945], Gilead again references a New York case accusing Scripts of conspiring with RxWholesale to hide assets, including Gilead inventory, to frustrate a judgment (¶ 318). However, that allegation has already been conclusively disproven since the creditor in that case with a security interest in RxWholesale's inventory previously amended its complaint to remove all allegations against Scripts.

In this case, if Scripts would have had the opportunity to contest Gilead's application for the asset freeze, it would have been able to establish that all of the available evidence suggests that Scripts is not likely to dissipate or secrete its assets in an effort to frustrate a potential future judgment. Now that this evidence is before the Court, it is appropriate to consider in deciding whether to maintain or reduce the asset freeze order.

It is also significant that even after reviewing all documents, products and other information obtained from all the ex parte seizures in this action, Gilead has still not established that Scripts has completed any actions with the specific intent to frustrate any judgment. "While plaintiff's arguments may have been sufficient to justify temporary relief on an ex parte basis, they are no longer sufficient now that defendants have had an opportunity to be heard." *BMaddox Enters, LLC v, Oskouie*, 2017 U.S. Dist. LEXIS 146766, *17 (S.D.N.Y. 2017) (dissolving asset restraining order where evidence of defendants' alleged fraudulent and infringing conduct before commencement of action not show an intent to frustrate a future judgment). "Absent any evidence

that defendants either have secreted assets or are about to do so in an effort to frustrate a future judgment, this argument fails." *Id.*, at *13.

Scripts further notes that in Gilead's initial application for an *ex parte* Asset Freeze Order against Scripts, Gilead submitted virtually no evidence that Scripts is likely to dissipate or secrete its assets. Gilead offered no declarations or other evidence specifically related to Scripts' assets and the likelihood that Scripts would dissipate its assets to avoid a possible judgment. Indeed, Gilead's Memorandum of Law, dated October 14, 2021, in support of the asset freeze request barely mentions Scripts. Instead, Gilead argues that "Scripts fits the same mold as previously named Distributor Defendants Safe Chain and ProPharma" and that "Scripts should not be given the opportunity to hide or spend its counterfeiting profits." (Gilead Memorandum of Law, pp. 57-58) Mere conclusory allegations based upon speculation such as this are wholly insufficient to support the contention that Scripts is likely to dissipate its assets or take action to evade judgment. *See e.g.*, *BMaddox Enters, LLC v, Oskouie*, 2017 U.S. Dist. LEXIS 146766, *15 (S.D.N.Y. 2017) ("[A]lthough plaintiff argued that it's 'safe to assume,' or that it is 'almost certain,' that defendants would remove assets from the United States, such arguments are little more than speculation and demonstrate, at most, that there is a possibility that defendants would secrete assets to frustrate a judgment.).

In summary, even after having access to all of Scripts documents and its communications, Gilead has presented no evidence from which this Court may infer that Scripts will divert its sales proceeds prior to the conclusion of this litigation or otherwise use these funds other than in the ordinary course of business. *Kebapci v. Tune Core, Inc.*, 2016 U.S. Dist. LEXIS 159054 (E.D.N.Y. Nov. 11, 2016). Indeed, even a wrongful use of funds does not infer evidence of an intent to frustrate a future judgment. *Sterling Ornaments Pvt., Ltd. V. Hazel Jewelry Corp.*,

2015 U.S. Dist. LEXIS 77331, at *3 (S.D.N.Y. June 9, 2015); *Haggiag v. Brown*, 728 F. Supp 286, 291 (S.D.N.Y. 1990). Further, a court may not rest its finding of the likelihood of future harm solely on past conduct, including past conduct in the infringement context before the commencement of the action. *BMaddox Enters, LLC v, Oskouie*, 2017 U.S. Dist. LEXIS 146766, *15 (S.D.N.Y. 2017). Accordingly, and on this basis alone, the Asset Freeze Order against Scripts should now be vacated. *See, e.g.*, *Haggiag v. Brown* (denying asset freeze where plaintiffs failed to present "any significant evidence of any massive dissipation of assets of the sort which would be required in order for the drastic remedy sought by plaintiffs to be appropriate.").

IV. THE PUBLIC INTEREST IS NOT SERVED BY MAINTAINING AN ASSET FREEZE OF SCRIPTS' FUNDS

Scripts respectfully submits that the public interest is not benefited by maintaining an Asset Freeze Order against Scripts issued *ex parte* where Gilead's legal claim of "counterfeiting" stands on very shaky ground. In addition, justice is not served when a plaintiff is able to prevail by simply freezing a defendant's financial assets such that it is forced out of business.

CONCLUSION

For all of the reasons set forth above, the Asset Freeze Order entered against Scripts should be vacated entirely. Alternatively, Scripts respectfully requests that the Asset Freeze Order be modified in accordance with the facts discussed herein.

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Respectfully submitted,

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